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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,862

03/04/2004

Karl F. Popp

24948-X

5241

20529

7590

07/05/2007

NATH & ASSOCIATES

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Alexandria, VA 22314

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,862	Applicant(s) POPP, KARL F.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt of IDS dated 11-30-04, 10-1-04, 9-30-04 and 5-25-04 is acknowledged.

Claims 1-57 are pending.

Instant claim 1 is directed to a method of treating rosacea in a patient comprising topically administering to the skin of a patient a composition comprising a storage-stable mixture of benzoyl peroxide and clindamycin. Claim 29 recites a method for reducing or eliminating mite organisms that cause rosacea, using the above composition.

Independent claim 44 recites a method of treating rosacea in a patient having sensitive skin.

Double Patenting

Claims 1-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/617191, and over claims 1-63 of copending Application No. 10/787231 in view US 6,150,381. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both the copending applications recite the same composition for treating bacterial disorders of skin and bacterial infections. While the co-pending claims do not state rosacea, US 6150381 to Subbiah teaches that rosacea as a skin condition associated with acne and caused by propionic acne (col. 2-3), as a result of bacterial infection. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to use the composition of 10/617191 or **copending application** to treat rosacea caused by bacterial skin infections. A skilled artisan would have expected a successful

treatment of skin conditions caused by bacterial infections, including rosacea, with the composition of the above co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26, 28 and 44-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Baroody et al (Baroody) in view of US 6,150,381 and Rosen et al (Pharmacotherapy, 1981).

Baroody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months (col. 2, L 3-66). Baroody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and

Art Unit: 1615

clindamycin is combined with a carrier, and further with a gelling agent such as Carbopol (col. 4, L 1-43). Table 1 of Baroody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5, which includes the pH of the instant claims. Baroody discloses applying the composition once or twice daily (col. 7, L 25-35). For claimed stability, Baroody shows that the composition is stable over a long period of time (table 7 and 8). Baroody does not specify the age group of patients that are treated with the composition. However, the examples show that the composition is highly effective against acne (col. 15-16) and therefore the composition of Baroody is effective against all the age groups (including those claimed). With respect to the viscosity, Baroody discloses that initial viscosity of benzoyl peroxide in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000. Table 1 teaches humectant in the composition, which meets the requirement of additional components.

Baroody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of instant claims, percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. However, Baroody also recognize the same factors i.e., pH, viscosity etc., that affect the stability (result-affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long

Art Unit: 1615

periods of time because the teachings of Baroody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin and employed for the same purpose similar to the instant invention i.e., treatment of acne or other skin related conditions that require benzoyl peroxide and clindamycin combination. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

For the instant limitation of a method of treating rosacea, Baroody teaches that the composition is effective for acne but does not specifically state the bacterial conditions such as folliculitis, erythrasma etc.

US '381 teaches a method of treating skin disorders caused by bacterial infections, including acne and describes the claimed conditions such as folliculitis, erythrasma as associated with acne (lines bridging col. 2-3). '381 teaches a combination of active agents such as sclareol or sclareolide compounds and also suggest adding benzoyl peroxide (claims), as effective against several bacterial species such as E. coli, S. aureus etc (example 1).

Rosen teaches that clindamycin is effective in treating acne vulgaris and also for conditions such as erythrasma, rosacea etc (abstract only).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to use the composition of Baroody for treating several bacterial skin disorders including those caused by acne bacterium i.e., rosacea etc., because '381 suggests that compositions comprising sclareolide and benzoyl peroxide

Art Unit: 1615

as effective for the bacterial skin disorders such as rosacea (above) and Rosen teaches clindamycin is effective for treating acne as well as the conditions such as folliculitis etc. Thus, a skilled artisan would have expected to inhibit not only acne causing bacteria but also the skin conditions associated with the infection, with the composition of Baroody.

Claim 27 and 29-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Baroody et al (Baroody) in view of US 6,150,381 and Rosen et al (Pharmacotherapy, 1981) and Roihu et al (J. Cutan. Pathol).

Baroody, discussed above fails to teach a method of reducing or eliminating mite organisms that causes rosacea of claims 29-43 or the rosacea that exhibits mite organism infestation. Rosen teaches that a combination of sclareolide and benzoyl peroxide is effective for bacterial disorders such as acne and conditions such as rosacea.

Roihu teaches hair follicle mites *D. folliculorum* and *D. brevis* and their role in rosacea. Roihu observed that *Desmodex* mites were found that the mites were prevalent in rosacea group and were significantly higher than in the rest of the study population. Roihu also observed that *Desmodex* also plays a role in inflammatory reaction in acne. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention that the inflammation reaction acne rosacea is also prevalent in *Desmodex* infestation, in addition to the those caused by bacterial infections such as acne vulgaris and accordingly, a skilled artisan would have employed

the composition of Baroody comprising benzoyl peroxide to treat D. folliculorum or D. brevis with an expectation reduce the mites and in turn the inflammatory conditions i.e., acne rosacea.

Rejection under 35 USC 112

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "rosacea exhibits effects selected from mite infestation", which is vague because rosacea itself is a condition that is a result of mite infestation. How can rosacea exhibit effects selected from mite *infestation*? A *clarification is requested*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 1615
June 24, 2007



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER